This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21

See attached form for additional information.

Interagency Report Control No.: 11-30-05

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 87-R-0022
CUSTOMER NUMBER: 21308

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Ibex Preclinical Research, Inc.
1072 West Rsi Drive
Logan, UT 84321

Telephone: (435) -881-1496

"A" by Dr. Watkins 12/23/05

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	48	6 (See Attached)	54
5. Cats	0	0	0	0	
6. Guinea Pigs	0	0	0	0	
7. Hamsters	0	0	0	0	
8. Rabbits	0	80	30	0	110
9. Non-human Primates	0	0	0	0	
10. Sheep	0	18	0	0	18
11. Pigs	0	0	53	0	53
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6), (b)(7)c

pe or Print)

DATE SIGNED 11/28/05

NOV 29 2005

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number 87-R-0022, Ibex Preclinical Research, Inc.
2. Number of animals used in this study. **6** - Three separate dose escalation studies were conducted utilizing two animals each.
3. Species of animals used in the study. **CANINE**
4. Explain the procedure producing pain and/or distress.

   The category E protocols are Acute Maximum Tolerated Dose or dose escalation studies for new drugs being developed for human use. The purpose of this study is "to identify doses causing no adverse effect and doses causing major (life-threatening) toxicity. " (from CDER, Guidance for Industry: Single Dose Acute Toxicity for Pharmaceuticals", pp1-2 (1996).

   The procedure entails dosing with a predetermined dosage of a drug and evaluating for signs of toxicity. Animals are closely observed after dosing. After a drug wash-out period of at least two days, animals are dosed again at a higher dose, typically a dose 2-fold higher. This process is repeated until major toxicity is observed or until an animal receives 5 doses, whichever comes first. This is referred to as a dose escalation study in the FDA Guidance Documents (see item 2, paragraph 6 below.). The potential for unrelieved pain and distress is present in these studies, indeed the FDA regulatory documents require that a dose be identified that causes major, life-threatening toxicity.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Tests were Federally mandated, see Item 6.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102): Agency,

   1. Center for Drug Evaluation and Research (CDER)(FDA). Guidance for Industry: Single Dose Acute Toxicity Testing for Pharmaceuticals", pp1-2, 1996.
   2. ICH Harmonized Tripartite Guideline: Guidance for Industry: M3 Non-clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals, pp. 1-7, (2000), FDA Center for Drug Evaluation and Research (CDER) and FDA, Center for Biologics Evaluation and Research (CBER). (Section IV, Single Dose Toxicity Studies allows for a dose escalation study to be used as an acceptable alternative to a single dose design)

(b)(6), (b)(7)c

November 28, 2005